UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/039,177	03/13/98	MIYAZONO K	LUD-5539

HM22/0731

FULBRIGHT & JAWORSKI LLP
666 FIFTH AVENUE
NEW YORK NY 10103-3198

EXAMINER	
ROMEO,D	
ART UNIT	**PAPER NUMBER**
1647	15

DATE MAILED: 07/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/039,177	Miyazano et al.
Examiner	**Group Art Unit**
David S. Romeo	1647

☒ Responsive to communication(s) filed on *8 May 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-28* is/are pending in the application.

Of the above, claim(s) *1-20, 25, and 27* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21-24, 26, and 28* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *16*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1647.

2. Claims 1-28 are pending. Claims 1-20, 25, 27 remain withdrawn from further consideration by the examiner, 37 CFR1.142(b), as drawn to non-elected inventions. Claims 21-24, 26, 28 are being examined to the extent that the read upon methods using agents that promote Smad1 phosphorylation and to the extent that they read upon the elected TGF-β species of agent.

3. Any objection or rejection of record that is not maintained in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 21-23, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by either one of Yingling (u10)[1] or Leichleider (v10). Applicants' arguments have been fully considered but they

[1]References cited by the examiner are in an alphanumeric format, such as "a1", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

are not persuasive. All that the claims require is contacting a cell with TGF-β. TGF-β is a molecule which is inherently capable of activating phosphorylation of Alk-1, binding to the extracellular domain of Alk-1, and facilitating interaction of Alk-1 and a TGF-β type II receptor. Either of Yingling's or Leichleider's cells are capable of expressing a gene which is activated by phosphorylated Smad1, absent evidence to the contrary.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Yingling (u10) or Leichleider (v10). Applicants' arguments have been fully considered but they are not persuasive. All that the claims require is contacting a cell with TGF-β. TGF-β is a molecule which is inherently capable of activating phosphorylation of Alk-1, binding to the extracellular domain of Alk-1, and facilitating interaction of Alk-1 and a TGF-β type II receptor. Either of Yingling's or Leichleider's cells are capable of expressing a gene which is activated by phosphorylated Smad1, absent evidence to the contrary.

6. The declaration under 37 CFR 1.132 filed 05/08/00 is insufficient to overcome:

a. the rejection of claims 21-23, 26 under 35 U.S.C. 102(b) as being anticipated by either one of Yingling (u10) or Leichleider (v10);

b. the rejection of claim 24 under 35 U.S.C. 103(a) as being unpatentable over either one of Yingling (u10) or Leichleider (v10);

as set forth in the last Office action because: All that the claims require is contacting a cell with TGF-β. TGF-β is a molecule which is inherently capable of activating phosphorylation of Alk-1, binding to the extracellular domain of Alk-1, and facilitating interaction of Alk-1 and a TGF-β type II receptor. Either of Yingling's or Leichleider's cells are capable of expressing a gene which is activated by phosphorylated Smad1, absent evidence to the contrary.

7. The declaration filed under 37 CFR 1.132 filed 05/08/00 is sufficient to overcome the rejection of claim 28 under 35 U.S.C. 103(a) as being unpatentable over either one of Yingling (u10) or Leichleider (v10) as taken in view of Basson (w10).

New formal matters, objections, and/or rejections:

Formal Matters

8. The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See Table 2 at page 20 and Figures 1, 2, 3, 5. This is not meant to be exhaustive list of instances wherein the specification fails to comply. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the

sequence rules. Applicant may bring the Figures into compliance by amending either the Figures or the "Brief Description of the Drawings" to recite the appropriate sequence identifier. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing."

Correction is required.

Claim Rejections - 35 USC § 102

9. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Ladher (u15). Ladher teaches a method comprising contacting Xenopus embryos, a first sample of cells which express and phosphorylate Xmad1, Smad1, with BMP-4, an agent which activates phosphorylation of Smad1, removing transcripts from the first sample of cells, and comparing those transcripts with the transcripts of a second sample of xenopus embryos not treated with BMP-4 (page 2385, column 2, full paragraphs 1-3; page 2387, column 2, full paragraph 1; Figure 5). Xom is a gene whose activation is effected by phosphorylation of Smad1.

Conclusion

10. No claims are allowable.

11. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Xom is also known as Xvent-2. See Trindade (v15), Abstract. Xvent-2 gene expression is activated by phosphorylated Smad1. See Gouedard (w15), Abstract and sentence bridging pages 12-13. Xmad1 transduces a signal for BMP4. See Graff (x15), Abstract. Smad1 and Xmad1 are alternative designations of the same molecule. See Heldin (x10), legend to Figure 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

David Romeo
David Romeo
Primary Examiner
July 28, 2000